EXPERIMENTAL VENTRICULAR DEFIBRILLATION WITH AN AUTOMATIC AND COMPLETELY IMPLANTED SYSTEM

John C. Schuder, Harry Stoeckle, Jerry H. Gold,
Joe A. West, and Prabhaker Y. Keskar

The employment of highly trained ambulance crews prepared to perform emergency cardiac resuscitation procedures and the installation of coronary care units with extensive monitoring and therapeutic capabilities are among the measures which are being taken to reduce the death rate of patients in the period following a coronary heart attack. However, even if these measured for obtaining improved care of the coronary patient were to become universally used, an appreciable percentage of people who suffer a myocardial infarction would die before obtaining either emergency medical attention or the more sophisticated care available in a coronary care facility.

If the death rate during the first few minutes following a coronary occlusion is to be reduced, provisions must be made for either automated therapeutic intervention or the prompt application of therapeutic measures by the patient himself or by non-medical personnel. Ventricular fibrillation is one of the possible consequences of a myocardial infarction and its occurrence is presumably responsible for many of the very early deaths. Electroshock is an effective way of reversing ventricular fibrillation. The animal study reported in this manuscript was designed as a preliminary step in the evaluation of the feasibility of implanting standby automatic ventricular defibrillation systems for supplying an electroshock, when required, to high risk patients.

DESCRIPTION OF SYSTEM

A block diagram of the completely implantable defibrillation system is shown in Figure 1. A photograph of the system, in the form in which it was used in our 2 more successful experimental procedures, is shown in Figure 2. The total system, before being covered for implantation, weighed 1037 Gm. A slightly different version of the totally implantable system using a smaller capacitor bank, a slightly smaller battery pack, and a larger fibrillation detector was used in our first experimental procedure. For the sake of concreteness, the detailed discussion in this portion of the manuscript is focused upon the specific system shown in Figure 2.

The primary source of energy for the system is a 19.5 volt battery pack which consists of 13 Mallory MN1500 alkaline cells in series. The dc-to-dc converter utilizes a Microtran type M8115 transformer and 2 2N1050A transistors in a relatively conventional switching circuit. Short term energy storage is provided by the 600 Mfd. capacitor bank which is made up of 3 Cornell-Dubilier type BR200-450 capacitors in parallel. The fibrillation detector consists of a 2-stage amplifier followed by a 2N2328 silicon controlled rectifier. Although the main source of energy for the fibrillation detector circuit is the alkaline battery pack, a very small 15 volt Eveready type 504 battery is used to provide voltage regulation.

An abbreviated circuit diagram of the pulse generator is shown in Figure 3. The waveform of current which the generator supplies is dependent upon the capacitance of the capacitor bank, the chest resistance of the animal, and the capacitance of the duration-determining capacitor C. Waveform A, as shown in Figure 4, was used for our first completely implanted automatic defibrillation study and in all of our non-automatic procedures. The animals used in these studies had chest resistance values in the neighborhood of 35 ohms. Waveform B, as shown in Figure 5, was employed for our more successful studies with the completely implanted-automatic system. The animals used in these studies had chest resistances of about 45 ohms. The details discussed in the following paragraph refer to the generation of waveform B.

In brief, the operation of the pulse generator is as follows: When the capacitor bank potential reaches about 500 volts. the 2N2328 silicon controlled rectifier breaks down and initiates discharge of the capacitor bank through the 5 ohm resistor and the patient. If the chest resistance is 45 ohms, the initial value of current is 10 amperes. But the breakdown of the 2N2328 also initiates the charging of the capacitor C in the cathode-gate circuit of the 2N1777A silicon controlled rectifier. After 12 msec., this capacitor voltage is sufficient to trigger the 2N1777A into conduction. This effectively reduces the current through the chest electrodes and the 2N2328 to zero, thus yielding waveform B shown in Figure 5. The discharge of the capacitor bank is then completed through the series circuit consisting of the 5 ohm resistor and the 2N1777A.

The operation of the complete defibrillation system is as follows: Under standby conditions, the fibrillation detector senses the presence of R waves and no turn-on signal is delivered to the dc-to-dc converter. The standby

From the Thoracic and Cardiovascular Section, Department of Surgery, and the Department of Pediatrics, University of Missouri, Columbia, Missouri. This investigation was supported by PHS research grants HE-05854 and HE-09729 from the National Heart and Lung Institute and a grant from the Missouri Heart Association. This study was conducted during the tenure of Dr. Schuder as an Established Investigator of the American Heart Association.

power requirement of the system is only that required for the fibrillation detector and is in the order of 2 milliwatts. The absence of R waves for a period of 5 sec. causes the fibrillation detector to deliver a turn-on pulse which triggers the dc-to-dc converter into operation.

Activation of the dc-to-dc converter yields a signal which closes the contacts on a reed relay and thus protects the solid state electronics of the fibrillation detector from damage during the defibrillatory shock. Activation of the converter also initiates charging of the 600 Mfd. capacitor bank. Depending upon the status of the battery pack, 12-35 sec. are normally required to charge the capacitor bank to 500 volts.

When the capacitor bank reaches 500 volts, the pulse generator delivers a current waveform (Figure 5) to the chest electrodes. The pulse generator circuit also provides a signal to open the contacts of a reed relay which, through a 2N307 transistor switch, opens the collector circuit and thus turns off the dc-to-dc converter. With the deactivation of the converter, the fibrillation detector is again activated and the system once more is in a position to sense the presence or absence of R waves in the electrocardiogram. If defibrillation has been successfully accomplished, the system will remain in its standby state. If fibrillation persists, the cycle of events described above will be repeated and another electroshock delivered to the experimental animal.

Non-automatic systems. Prior to our development of the automatic defibrillation system, 2 non-automatic systems were studied. These systems utilized the same capacitor storage-pulse generator concept as used in the automatic system. The completely implantable system illustrated in Figure 6 is similar to the system shown in Figure 1, except that the dc-to-dc converter is switched on and off by means of a manually operated switch which can be activated through the skin. Figure 7 illustrates a system in which the battery and an oscillator are external to the body and radio frequency inductive coupling is used for the transmission of the energy required for charging the implanted capacitor bank. It has been shown that power levels far greater than required for the present application can be transmitted easily through the skin[1,2]. Once the capacitor potential reaches 500 volts, the pulse generator delivers the defibrillatory shock automatically. In our experimental study, the weight of that part of the system implanted within the animal was about half that required for the totally implanted automatic system.

EXPERIMENTAL PROCEDURE

For the short term studies reported in this manuscript, the various individual units of the completely implantable automatic defibrillation system were prepared for implantation by covering them with rubber gloves. Temporary seals between the rubber and the leads were made by using silastic beads which were further reinforced by appropriate sutures on both sides of the silastic and around the rubber-lead bundles. The stainless steel chest electrodes, which are 7.5 cm. in diameter, were covered with epoxy on one side in order to reduce the non-effective current in the chest wall.

The system was then implanted in an anesthetized dog in which a bipolar catheter had previously been inserted through a vein into the right ventricle. The 2 chest electrodes were implanted between the pectoralis major muscle and the rib cage. The right electrode was relatively high on the chest and slightly to the right of midline. The left electrode was approximately over the apex of the heart.

The needle electrodes used for the electrocardiographic signal pickup were positioned in the musculature of the chest wall so as to furnish a signal with a prominent R wave. One needle was placed above and somewhat to the left of the right chest electrode. The other was positioned below and to the right of the left chest electrode.

The remainder of the apparatus was implanted subcutaneously in the abdominal region. After the apparatus was implanted, the various incisions were closed. One experimental animal with an implanted defibrillation system is shown in Figure 8. The external electrocardiographic leads shown in the photo are for conventional monitoring purposes and are not part of the implanted defibrillation system.

In evaluating the system, fibrillation was induced in the anesthetized animal with a 1-2 volt, 60 hertz shock applied via the catheter to a bipolar electrode tip in the right ventricle. Fibrillation was confirmed by observation of the monitoring oscilloscope. The time of turn-on of the dc-to-dc converter was evident by the appearance of a high frequency artifact superimposed in the fibrillatory electrocardiographic signal. The time required for the implanted system to deliver the defibrillatory shock was observed and the success or failure of the shock noted by observation of the monitoring oscilloscope. In the event that defibrillation was not achieved with the initial shock, the system was, in general, left alone and permitted to automatically repeat the cycle until defibrillation was achieved. After defibrillation, the animal was allowed a period to recover and then fibrillation was again induced, with 3 or more min. always intervening between the start of successive trials.

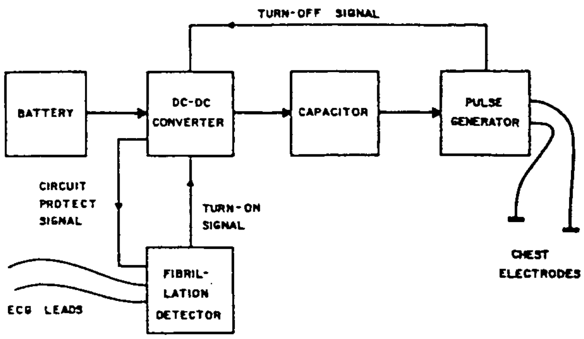

Figure 1. Block diagram of completely implantable automatic defibrillation system.

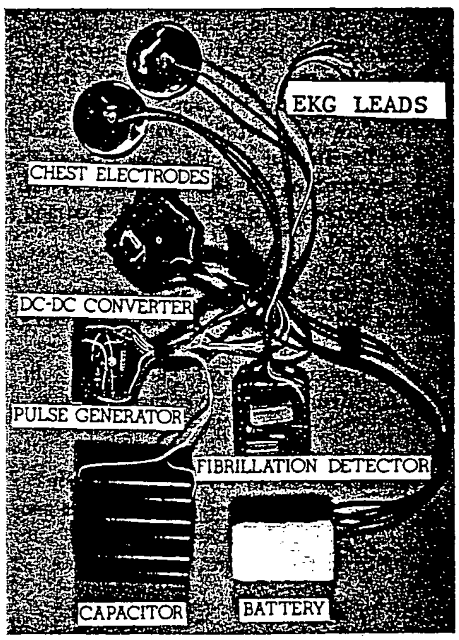

Figure 2. Completely implantable automatic defibrillation system in form used in some of the experimental procedures.

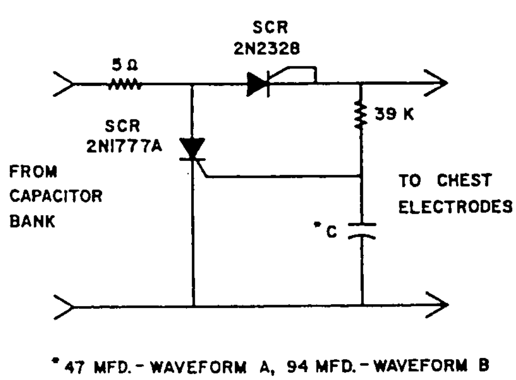

Figure 3. An abbreviated circuit diagram of the pulse generator.

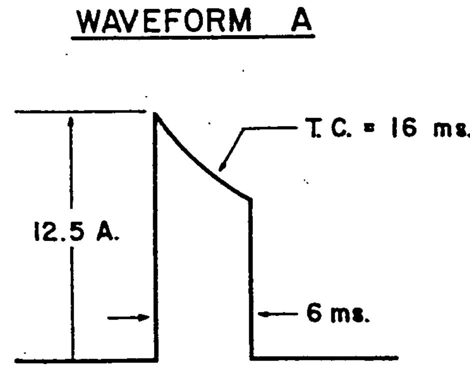

Figure 4. Approximate current waveform furnished by pulse generator when working from 400 Mfd. capacitor bank into 35 ohm chest resistance.

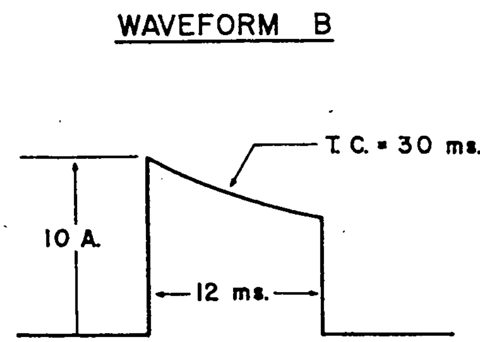

Figure 5. Approximate current waveform furnished by pulse generator when working from 600 Mfd. capacitor bank into 45 ohm chest resistance.

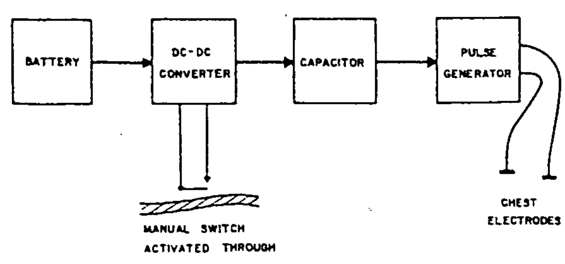

Figure 6. Block diagram of completely implantable and manually operated defibrillation system.

Non-automatic systems. The procedure for evaluating the non-automatic systems was similar to that outlined above, except that fibrillation was induced by transthoracic shock rather than via a catheter into the right ventricle.

EXPERIMENTAL RESULTS

Our experimental results with the totally implanted automatic defibrillation system are summarized in Table I.

TABLE I

DEFIBRILLATION RESULTS WITH TOTALLY IMPLANTED AUTOMATIC SYSTEM

Dog Number	Weight in Kg.	Waveform	Shocks Required to Defibrillate	Number of Episodes
			1	8
37700	22	A	2	3
			3	2
				Total = 13
			1	19
37701	15	B	2	1
				Total = 20
			1	20 (A. M.)
37695	16	B	1	20 (P. M.)
				Total = 40

The approximate electroshock waveform used with the first animal, dog number 37700, is sketched in Figure 4. On the basis of 35 ohms resistance between the electrodes, the shock delivers about 23 joules of energy to the chest. The total time interval between the induction of fibrillation and the application of the defibrillatory shock varied between 14 sec. early in the experimental period and 35 sec. toward the end of the period. This increase in time interval reflected a deterioration of the battery. Although external countershock was never required in this first animal, intervention with drug therapy and massage was needed to obtain an effective beat following some of the automatic defibrillation shocks. Because of the repeated shocks required in 5 of the 13 episodes, the system actually delivered a total of 20 shocks during the experimental period.

The approximate electroshock waveform used with the second animal, dog number 37701, is shown in Figure 5. On the basis of 45 ohms resistance between the electrodes, the shock delivers about 37 joules of energy to the chest. The total time interval between the induction of fibrillation and the application of the defibrillatory shock varied between 17 sec. at the start of the experimental period and 23 sec. toward the end of the period. In 19 of the 20 procedures, defibrillation was achieved with a single shock. Neither drug therapy nor massage was required.

The third animal, dog number 37695, was also evaluated with the waveform shown in Figure 5. Twenty fibrillation-defibrillation procedures were carried out in the morning and 20 more in the afternoon. All were successful. The total time period between the start of fibrillation and the defibrillatory shock varied from 16-23 sec. in the morning session and 24-40 sec. in the afternoon session. Again, neither drug therapy nor massage was required.

Non-automatic systems. Our experience with the totally implanted system which utilized a manual switch is summarized in Table II. In this particular experimental procedure, the first battery pack was surgically removed after the first 14 episodes and a second battery pack implanted. In 2 of the 14 episodes with the first battery pack, the implanted system failed to defibrillate with 2 shocks and externally applied defibrillatory shocks were used to save the animal. With the second battery pack, all 20 episodes yielded success with the first defibrillatory shock. Our results with the radio frequency inductively coupled system are summarized in Table III.

TABLE II

*DEFIBRILLATION RESULTS WITH TOTALLY IMPLANTED MANUAL SWITCH SYSTEM

Battery	Shocks Required to Defibrillate	Number of Episodes
84 Eveready type N24 nickel-cadmium cells in series-parallel	1	12
	After failure with 2 shocks, external unit used.	2
12 Mallory type MN 1500 cells in series	1	20
		Total = 34

*Dog number 38074, weight 19 Kg., waveform A.

TABLE III

*DEFIBRILLATION RESULTS WITH R. F. COUPLED SYSTEM

Shocks Required to Defibrillate	Number of Episodes
1	10
2	10
	Total = 20

*Dog number 38074, weight 19 Kg., waveform A.

DISCUSSION

In contrast to the waveform of current supplied by most commercial transthoracic defibrillators which employ an inductor in series with the energy storage capacitor, our defibrillation system delivers a shock which has a very fast rate of increase of current with time at the start of the pulse and a very high rate of decrease of current with time at the end of the pulse. Carefully controlled basic studies have convinced us that these high rates of change of current are not injurious to the heart and do not adversely influence the outcome of a defibrillation effort[3-5]. Other basic studies have shown that trapezoidal shocks can be very effective in reversing ventricular fibrillation[6]. Consequently, there is every reason to believe that quasi-trapezoidal shocks generated by the silicon controlled rectifier type of pulse generator can also be effective in reversing ventricular fibrillation.

The values for amplitude, time constant, and duration of the 2 waveforms used in the work reported in this manuscript were selected because such pulses could be generated with silicon controlled rectifiers which were easily available and because our previous basic studies with trapezoidal waveforms convinced us that waveforms with these parameter values would be relatively effective[6]. These same studies clearly suggest that improved results will follow from increasing the initial current level to 20 amperes or more. To obtain this increase in current level will require either the employment of higher voltage silicon controlled rectifiers or in-series circuits for units of the type currently used.

When first implanted, at least, the defibrillation system described, with the chest electrodes on the rib cage, appear to require appreciably less energy for a given level of effectiveness than does a corresponding external transthoracic system with electrodes held on the surface of the chest. One reason for this is that the measured resistance between electrodes on the rib cage is considerably less than that measured between well jellied electrodes on the surface of the chest. However, it remains to be determined whether the reduction in resistance which is realized in the period immediately following implantation of the chest electrodes will be experienced on a chronic basis. Furthermore, although we have not yet studied the matter carefully, we expect that the one face insulated-one face conducting nature of the implanted electrodes may yield a more favorable current distribution with a somewhat greater percentage of the total current passing through the heart than is experienced with the external transthoracic approach.

In any event, the level of energy which will have to be delivered in a clinical application of the system will have a very important bearing on the weight of the capacitor bank and battery pack which will be required.

In the present system, the decision to turn on the dc-to-dc converter and to supply a shock is based on the absence of R waves in the electrocardiographic signal for a period of 5 sec. While our relatively simple detector has functioned well in the experimental animal, it is clearly not sufficiently sophisticated in its decision making capabilities to yield satisfactory results in the presence of the more complex arrhythmias which sometimes occur in coronary patients. We anticipate that a continued effort will be required to develop a satisfactory detector within the size and power constraints which the problem imposes.

A discussion of the problem of minimizing battery weight is complicated by the fact that battery specifications are closely tied to the energy stored in the capacitor bank, acceptable charging time, number of defibrillatory shocks needed, and standby power needs. However, because of the need to charge the capacitor bank in a relatively short time period, the power/unit weight ratio becomes an unusually important figure of merit in this kind of application. We anticipate that the present battery weight of 322 Gm. can be decreased if the same energy/shock is retained or, alternatively, a considerable increase in the energy/shock level can be achieved with the same battery weight. The problem of the time interval between reoperation for battery replacement is closely associated with standby power requirements for the fibrillation detector circuit. Very rough calculations suggest that with our present fibrillation detector and battery, replacement would be required at yearly intervals. While the standby power requirements for our present type of fibrillation detector could certainly be reduced considerably, a more sophisticated fibrillation detector might require more power and suggest the desirability of using radio frequency inductive coupling for recharging an internal battery.

The use of an automatic defibrillation system on a clinical basis would carry some risk of electrical shock to people who might be in direct contact with the patient while a defibrillatory shock was being delivered. This risk would appear to be minimal except for those who might be involved in rendering medical aid during acute cardiac episodes or other illnesses. To minimize this drawback to the automatic defibrillation system, an on-off switch which could be activated through the skin and used for temporarily deactivating the system would appear to be desirable.

Non-automatic systems. Although perhaps not as attractive as the completely implanted automatic system, the 2 non-automatic systems would allow the spouse of the patient, for example, to deliver emergency therapy in the home. Of the 2 non-automatic systems, the one involving radio frequency inductive coupling offers considerably less internal weight and volume and freedom from the need of reoperation for battery replacement. It would be easy to use in that it would merely be necessary to turn on the lightweight external battery-inverter-coil unit, place it over the implanted receiving coil, and wait until the defibrillatory shock is delivered. On the other hand, the radio frequency unit would require that the external unit be easily available for use in case of need. The other non-automatic system, being totally implanted, would always be available when needed, and would require only activation of the manual switch through the skin.

CONCLUSION

On the basis of the experimental results presented and theoretical considerations, we believe that it is likely that automatic and completely implantable ventricular defibrillation systems can be developed for clinical use.

ACKNOWLEDGMENT

The authors wish to thank Mr. B. J. McClatchey who served as the surgical research technician for the project.

REFERENCES

1. Schuder, J. C., Stephenson, H. E., Jr., and Townsend, J. F. High-level electromagnetic energy transfer through a closed chest wall. IRE International Convention Record, 9:119, pt 9, 1961.
2. Fuller, J. W. Apparatus for efficient power transfer through a tissue barrier. IEEE Trans. Biomed. Eng., BME-15:63, 1968.
3. Rahmoeller, G. A., Nellis, S. H., Schuder, J. C., Stoeckle, H., and Mackenzie, J. W. Influence of rise time on the effectiveness of defibrillatory shocks. Proc. Ann. Conf. Eng. Med. Biol., 8:25, 1966.
4. Schuder, J. C., Rahmoeller, G. A., Nellis, S. H., Stoeckle, H., and Mackenzie, J. W. Transthoracic ventricular defibrillation with very high amplitude rectangular pulses. J. Appl. Physiol. 22:1110, 1967.
5. Stoeckle, H., Nellis, S. H., and Schuder, J. C. Incidence of arrhythmias in the dog following transthoracic ventricular defibrillation. Circ. Res., 23:343, 1968.
6. Schuder, J. C., Rahmoeller, G. A., and Stoeckle, H. Transthoracic ventricular defibrillation with triangular and trapezoidal waveforms. Circ. Res., 19:689, 1966.

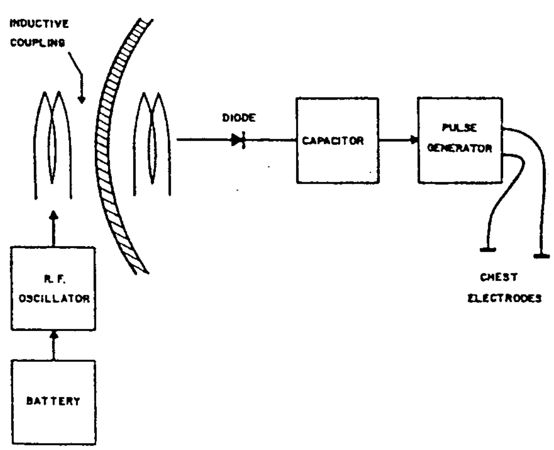

Figure 7. Block diagram of defibrillation system in which a battery pack, oscillator, and coil are outside the body and inductive coupling is used to charge capacitor bank.

Figure 8. Experimental animal with automatic ventricular defibrillation system implanted.